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Paper No.

ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON DC 20007-5109 MAILED

FEB 1 6 2010
OFFICE OF PETITIONS

In re Application of
Rajeev A. Jain, Jon Swanson,
:

Robert Hontz, John Devane,
Jenneth Iain Cumming, Maurice

Joseph Anthony Clancy, and

Janet Elizabeth Codd : DECISION ON TWO RENEWED Application No. 09/337,675 : PETITIONS PURSUANT TO

Filing Date: June 22, 1999 : 37 C.F.R. §\$ 1.48 AND 1.183

Attorney Docket Number: 029318/0497

Title: CONTROLLED-RELEASE

NANOPARTICULATE COMPOSITIONS

Background

This is a decision on the two renewed petitions pursuant to 37 C.F.R. §§ 1.48 and 1.183, concurrently filed on April 15, 2009. Petitioner has requested the correction of the inventorship of the present application, along with the waiver of 37 C.F.R. § 1.48(a)(3).

In short, Petitioner has requested that Gary Liversidge be added as an inventive entity, and that the Office waive the requirement that the applicant provide an oath or declaration by the actual inventors (Petitioner has submitted declarations that have been executed by each of the inventors save Mr. Cumming).

The renewed petition pursuant to 37 C.F.R. § 1.48(a)(3) is **DISMISSED**.

The renewed petition pursuant to 37 C.F.R. § 1.183 is DISMISSED.

A discussion follows.

Applicable Rules

37 C.F.R. § 1.48(a) sets foth, in toto:

- (a) Nonprovisional application after oath/declaration filed. If the inventive entity is set forth in error in an executed § 1.63 oath or declaration in a nonprovisional application, and such error arose without any deceptive intention on the part of the person named as an inventor in error or on the part of the person who through error was not named as an inventor, the inventorship of the nonprovisional application may be amended to name only the actual inventor or inventors. Amendment of the inventorship requires:
- (1) A request to correct the inventorship that sets forth the desired inventorship change;
- (2) A statement from each person being added as an inventor and from each person being deleted as an inventor that the error in inventorship occurred without deceptive intention on his or her part;
- (3) An oath or declaration by the actual inventor or inventors as required by § 1.63 or as permitted by §§ 1.42, 1.43 or § 1.47;
- (4) The processing fee set forth in § 1.17(i); and
- (5) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter).

37 C.F.R. § 1.183 sets forth, in toto:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, sua sponte, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in § 1.17(h).

Procedural History

Two petitions pursuant to 37 C.F.R. §§ 1.48 and 1.183 were concurrently filed on July 3, 2008. The former was supplemented via a submission on July 17, 2008. Petitioner provided, *inter alia*, the required petition fees, the written consent of the assignee coupled with a statement pursuant to 37 C.F.R. § 3.73(b), a statement from the person being added as an inventor that the error in inventorship occurred without deceptive intention on his part, a Supplemental Application Data Sheet (ADS), and a declaration that has been executed by each inventor save Mr. Cumming.

Both petitions were dismissed via the mailing of a single decision on March 30, 2009, which indicated, *inter alia*, that a petition pursuant to 37 C.F.R. § 1.47(a) would need to be filed.

The requirement for a petition pursuant to 37 C.F.R. \S 1.47(a) is hereby withdrawn.

Analysis of the Renewed Petition Pursuant to Rule § 1.183

This renewed petition is being construed to contain a request for the waiver of 37 C.F.R. § 1.48(a)(3), which requires the submission of an oath or declaration by the actual inventors (each of the actual inventors have executed the declaration that was provided with the submissions of July 3, 2008 and July 17, 2008, but for Mr. Cumming, who allegedly cannot be located.)

In order to submit a grantable petition pursuant to 37 C.F.R. § 1.183, Petitioner must show (1) that this is an extraordinary situation where (2) justice requires waiver of the rule. <u>In re Sivertz</u>, 227 U.S.P.Q. 255, 256 (Comm'r Pat. 1985).

With this renewed petition, Petitioner has asserted, but has not established, that either condition exists in this case. specifically, the record does not support a finding that nonsigning joint inventor Cumming cannot be located. Petitioner has actual knowledge that the last-known address is no longer valid. 1 With the original petition, it was asserted that Internet searches that were performed for non-signing inventor Cumming.² However, the electronic record does not contain a copy of either the search terms or the search results. Without a copy of the search terms, the Office cannot ascertain whether the searches were sufficiently broad so as to provide a reasonable chance of success. Without a copy of the search results, the Office cannot ascertain whether any promising leads were obtained. record does not presently support a finding that Mr. Cummings cannot be located, the record does not support a finding that an extraordinary situation exists, such that justice requires the waiver of Rule 1.48(a)(3).

¹ Original petition pursuant to 37 C.F.R. § 1.183, paragraph 4.

² Original petition pursuant to 37 C.F.R. § 1.183, paragraphs 3 and 6. $\underline{\text{See}}$ $\underline{\text{also}}$ Arthur declaration of facts (two online directories and two online search engines were searched), Elliott declaration of facts (one online search engine was searched), and Willis declaration of facts (two online search engines were searched).

Analysis of the Renewed Petition Pursuant to Rule § 1.48(a)(3)

With the original petition, requirements (1) - (2) and (4) - (5) of Rule § 1.48 were satisfied. Regarding the third requirement, Petitioner has failed to provide an oath or declaration that has been executed by the actual inventors, as required by 37 C.F.R. § 1.63, and pursuant to the discussion above, this requirement has not been waived.

Conclusion

Any reply must be submitted within **TWO MONTHS** from the mail date of this decision. Extensions of time under 37 C.F.R. § 1.136(a) are permitted. The reply should include a cover letter entitled "Second Renewed Petitions pursuant to 37 C.F.R. §§ 1.48 and 1.183". This is not a final agency action within the meaning of 5 U.S.C § 704.

Any response to this decision should indicate in a prominent manner that the attorney handling this matter is Paul Shanoski, and may be submitted by mail, hand-delivery, or facsimile. Registered users of EFS-Web may alternatively submit a response to this decision via EFS-Web.

If responding by mail, Petitioner is advised <u>not</u> to place the undersigned's name on the envelope. Only the information that appears in the footnote should be included - adding anything else to the address will delay the delivery of the response to the undersigned.

Telephone inquiries regarding this decision should be directed to the undersigned at (571) 272-3225.

/Paul Shanoski/
Paul Shanoski
Senior Attorney
Office of Petitions

³ Mail Stop Petition, Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

⁴ Customer Window, Randolph Building, 401 Dulaney Street, Alexandria, VA, 22314.

^{5 (571) 273-8300-} please note this is a central facsimile number.

⁶ https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html

⁷ Petitioner will note that all practice before the Office should be in writing, and the action of the Office will be based exclusively on the written record in the Office. See 37 C.F.R. § 1.2. As such, Petitioner is reminded that no telephone discussion may be controlling or considered authority for any further action(s) of Petitioner.